

**IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TENNESSEE
WESTERN DIVISION**

**PETER K. LAW, Ph.D., and CELL
TRANSPLANTS ASIA, LIMITED,
a Hong Kong Limited Liability
Company,**

Plaintiffs,

v.

**BIOHEART, INC., a Florida
Corporation,**

Defendant.

No. 2:07-cv-2177

**BIOHEART, INC., a Florida
Corporation,**

Counter-Plaintiff,

v.

**PETER K. LAW, Ph.D., and CELL
TRANSPLANTS ASIA, LIMITED,
a Hong Kong Limited Liability
Company,**

Counter-Defendants.

MEMORANDUM OPINION AND ORDER

This matter came before the Court for a non-jury trial, which was held September 22-25, 2008. Plaintiffs Peter K. Law, Ph.D. and Cell Transplants Asia, Limited (collectively, “Plaintiffs”) bring several state law claims against Defendant Bioheart, Inc. (“Bioheart”). Bioheart has in turn asserted several state law counterclaims. The parties being diverse and the amount in controversy being more than \$75,000, jurisdiction is proper pursuant to 28 U.S.C. § 1332. After reviewing the evidence, hearing the testimony of the witnesses called by each party,

and weighing the credibility of those witnesses, the Court finds that Plaintiffs have failed to establish the claims in their amended complaint by a preponderance of the evidence. Similarly, the Court finds that Bioheart has established only two of its counterclaims by a preponderance of the evidence. All other causes of action are dismissed, and judgment is rendered for Bioheart as set forth herein.

I. FINDINGS OF FACT

A. Plaintiffs

In 1972, Peter K. Law¹ earned a Ph.D. in neurophysiology from the University of Toronto. (Tr. 48; Ex. 154.) He then completed a three-year post-doctoral fellowship in clinical neurophysiology at McMaster University in Hamilton, Ontario before becoming an assistant professor of neurology at Vanderbilt University.² (Tr. 48.) Leaving his position at Vanderbilt in 1979, Dr. Law joined the faculty of the University of Tennessee at Memphis, where he eventually became a tenured professor and remained for several years. (Tr. 48; Ex. 154.) In 1991, Dr. Law resigned his professorship at the University of Tennessee to launch the Cell Therapy Research Foundation (“CTRF”), a non-profit organization dedicated to developing cellular treatments for muscular dystrophy, particularly Duchenne muscular dystrophy. (Tr. 49, 198.) At the time Dr. Law separated from employment with the University of Tennessee, the University of Tennessee Research Foundation—the owner of patents developed by Dr. Law while in the university’s employ—granted to Dr. Law and his then research assistant, Tena Goodwin, rights to the patent application that eventually, through Dr. Law’s efforts, became U.S. Patent No. 5,130,141 (“‘141 patent”). (Tr. 193, 196-98.) Ms. Goodwin subsequently transferred her rights in this patent to Dr. Law in August 1996. (Tr. 265.) In addition to the ‘141 patent, Dr. Law has also developed other technologies that have been patented. (Tr. 76-78; Exs. 48, 162.)

Beginning in 1991 with the founding of CTRF, Dr. Law concentrated his scientific work on treating sufferers of muscular dystrophy both in the United States and abroad by means of

¹ Dr. Law is a citizen of both China and Canada. (Ex. 154.) He currently resides in Canada. (Tr. 47.)

² Dr. Law is thus by training a neurophysiologist; he is not a medical doctor. (Tr. 178.)

“Myoblast Transfer Therapy” (“MTT”). (Tr. 197-98, 201, 219-22.) MTT involves the transfer of a normal human genome to a genetically abnormal patient through the injection of cultured myoblasts. (Tr. 198.) A myoblast, sometimes called a satellite cell, is an immature skeletal muscle cell. (Tr. 50.) In the treatment of muscular dystrophy by MTT, a small number of cells are taken from a genetically normal donor. (Tr. 70-71; see Tr. 56.) Those cells are then cultivated into billions of additional cells over several weeks, and the cultivated cells are injected into the patient. (Tr. 70-71.) The implanting of cells from one person into another, such as in MTT, is known as an allogenic process. (Tr. 56.) By contrast, in an autologous process, the cells implanted are derived from cells extracted from the patient’s own body. (Tr. 55-56.)

In 1996, Dr. Law formed Cell Transplants Asia, Limited (“CTAL”), a Hong Kong limited liability company in which he owns a 99% interest; Dr. Law’s wife owns the remaining 1% interest. (Ex. 196 at 46-47; see Tr. 201-02.) The following year, Dr. Law formed Cell Transplants International, LLC (“CTI”), a Tennessee limited liability company, in order to commercialize his patents. (Tr. 218-19.) In 2004, Dr. Law allowed the Tennessee Secretary of State to administratively dissolve CTI. (Tr. 274.) CTI had become financially unsound and left numerous creditors at its dissolution. (Tr. 275.) Dr. Law testified that he always maintained CTI and CTAL as separate business entities. (Tr. 260.) CTI is not now and has never been a named plaintiff in this suit. (See D.E. #1: Pls.’ Compl; D.E. #3: Pls.’ Am. Compl.)

In 1999, Dr. Law and CTRF became the subject of an investigation by the Food and Drug Administration (“FDA”) after an inspection of CTRF’s laboratory revealed a number of deficiencies. (Tr. 203-05.) The FDA placed the MTT program, which at the time was in trials pursuant to an “investigational new drug” application (“IND application”),³ on clinical hold in October 1999, thereby precluding further trials and treatment. (Tr. 205, 214; Ex. 184.) In the summer of 2000, the FDA seized Dr. Law’s supply of myoblasts and notified Dr. Law that he had been disqualified as an FDA-approved clinical researcher. (Tr. 214-15; see Ex. 194.) Dr.

³ In order to proceed to human clinical evaluation of a product or treatment such as MTT or that being developed by Bioheart, it is necessary to file an “investigation new drug” or “IND” application with the FDA. (Tr. 554.) See generally 21 U.S.C. § 355; 21 C.F.R. § 312.1 et seq.

Law's myoblasts were destroyed by the FDA in February 2001. (Tr. 215.) In November 2002, the FDA notified him that it intended to conduct a hearing on his qualifications. (Ex. 185.) Dr. Law failed to appear at the FDA's hearing and did not otherwise contest the charges against him. (Tr. 212-13.) Finally, in October 2006, the FDA officially disqualified Dr. Law from serving as an investigator in clinical trials. (Tr. 213-14; Ex. 187.)

B. Bioheart

Bioheart, a Florida corporation, maintains its principal place of business in Sunrise, Florida. (D.E. #34: Bioheart's Ans., ¶ 2.) In 1999, Howard Leonhardt,⁴ a businessman with many years of experience in the biotechnology sector, formed Bioheart with the goal of developing and commercializing cellular therapies designed to repair or regenerate damaged human heart muscle. (Tr. 367, 370, 664.) After some initial research, Bioheart decided that it would utilize myoblasts, as opposed to other types of cells, in this process. (Tr. 370.)

"MyoCell" is the trade name of the product Bioheart ultimately developed. (Tr. 694.) MyoCell treatment involves first taking a skeletal muscle biopsy from the thigh of a patient who has suffered heart failure. (Tr. 665.) Myoblasts are then removed from the biopsied muscle tissue. (Id.) These myoblasts are isolated and cultured in a proprietary growth media, which causes the myoblasts to grow into millions or even billions of cells. (Id.) Finally, the cultured myoblasts are implanted into the damaged heart muscle by means of a catheter. (Id.) Bioheart's original plan did not call for Bioheart to culture myoblasts itself. (Tr. 516; see Tr. 717-18.) Bioheart instead planned to contract this responsibility to outside manufacturers—namely Dr. Law and his facility. (Tr. 516.)

As part of developing MyoCell, Bioheart sought out and acquired patents and other intellectual property that potentially possessed utility for its purposes. (Tr. 373.) Bioheart also maintained consulting relationships with several scientists working in the area of heart muscle

⁴ Plaintiffs named Mr. Leonhardt as a defendant as well, but the Court has previously granted a motion to dismiss the claims against him in his individual capacity. (D.E. #31: Order Granting in Part and Denying in Part Defs.' Mot. to Dismiss.) At the same time, the Court also dismissed Plaintiffs' civil conspiracy cause of action for failure to allege any facts that would support such a claim. (Id.)

regeneration, including a Duke University researcher, Dr. Doris Taylor. (Tr. 386.) Dr. Taylor informed Bioheart of Dr. Law, and as a result Mr. Leonhardt concluded that Dr. Law's '141 patent might cover at least part of the process being developed by Bioheart. (Tr. 373-75.) Bioheart, therefore, decided to contact Dr. Law in order to obtain rights to his '141 patent. (Tr. 373.)

C. The License Agreement

In early 2000, Dr. Law and Bioheart exchanged draft proposals for an agreement by which Bioheart would acquire a license to practice the '141 patent. (Exs. 8, 10, 16, 17.) At this time, Bioheart and Mr. Leonhardt were operating under the impression that Dr. Law's procedures were FDA-compliant and that he was in the process of conducting human clinical trials; in reality, this was precisely when Dr. Law's problems with the FDA were escalating. (Tr. 418-19, 425-26.) Dr. Law represented that he could greatly assist Bioheart in the development of its product, including by becoming Bioheart's supplier of cultured myoblasts. Reliance upon Dr. Law would, Bioheart believed, enable it to progress quickly into clinical studies and then to commercialization of MyoCell. (Tr. 420-21, 488-89.) Ultimately, both sides reached an agreement, producing the first contract ("License Agreement") at issue in this case. (Ex. 20.)

Mr. Leonhardt executed the License Agreement on behalf of Bioheart on February 7, 2000, and Dr. Law executed the License Agreement on February 9, 2000. (Id.) Dr. Law signed as Chairman and CEO of CTI, not in his individual capacity and not on behalf of CTAL. (Id.) The terms of the License Agreement, stated succinctly, are as follows:

- Sections 1-2. CTI/CTAL grants Bioheart a non-exclusive license for all patents related to heart muscle regeneration and angiogenesis for the life of the patents. Sublicensing by Bioheart is prohibited.
- Section 3. Bioheart agrees to pay CTI/CTAL \$500,000 for "research of mutual interest" within ninety days.

- Section 4. Bioheart agrees to “immediately” provide CTI/CTAL 600,000 shares of Bioheart stock at \$1.80 per share.⁵
- Section 5. Bioheart agrees to give CTI/CTAL an option to acquire an additional 600,000 shares at \$1.80 per share within thirty days.
- Section 6. Bioheart agrees to pay a 5% royalty on “gross sales” of all products and services that “directly read upon the claims” of the patents licensed.
- Section 7. Bioheart agrees to provide an antidilution agreement related to the shares of stock to be owned by Dr. Law, CTI, and/or CTAL.
- Section 8. Bioheart agrees to elect Dr. Law to its board of directors.
- Section 9. CTI/CTAL agrees to pursue infringers of Dr. Law’s patents.
- Section 10. Bioheart agrees to enter into an agreement with CTI/CTAL for the supply of cultured myoblasts within thirty days.
- Section 11. Bioheart agrees to pay \$3 million to CTI/CTAL upon initiation of “a human clinical study of Dr. Law’s patented technology with FDA approval in the United States[.]”
- Section 12. Bioheart agrees to pay \$5 million to CTI/CTAL upon FDA approval of its “method of heart muscle regeneration utilizing the patented technology.”
- Section 13. Dr. Law and CTAL agree to provide Bioheart a right of first refusal in the event either is approached by a Bioheart competitor seeking a license.

(Ex. 20: License Agreement.) Mentioned in the preamble to the License Agreement is a \$500,000 payment, which Bioheart paid upon Dr. Law’s execution of this contract. (Id.; Tr. 388.) Bioheart did not, however, make the second \$500,000 payment to fund research of mutual interest within the ninety days specified in Section 3 of the License Agreement. (Tr. 389.) Additionally, CTI, CTAL, and Dr. Law never acted to purchase stock under Sections 4 and 5. (Tr. 389-90.)

⁵ Bioheart’s stock at the time was otherwise selling for \$8.00 per share. (Tr. 556.)

Around the time that the License Agreement was entered into, Bioheart decided to rely upon Dr. Taylor's processes, which are very similar to Dr. Law's, and to use Dr. Law's cell culturing media. (Tr. 429-30.) Dr. Law repeatedly made representations to Mr. Leonhardt that he and CTI/CTAL could be Bioheart's supplier of cultured myoblasts, and Bioheart anticipated that they would act as its supplier. (Tr. 425-27; cf. Ex. 34.)

D. The Addendum

Shortly after execution of the License Agreement, the parties recognized the need for revisions and modifications to its terms as well as the need to enter into additional agreements. (Tr. 560-62; Ex. 42.) Specifically, there was a need to finalize an agreement on the supplying of myoblasts (Tr. 561) and to obtain a license for Dr. Taylor's research at Duke University (Tr. 560, 571). The parties also appeared to be unclear on the parameters of Bioheart's right of first refusal and to be unclear as well in their understanding of exactly what events would cause the \$3 million milestone payment to become due. (Tr. 561-62.) Bioheart concedes that the terms of the License Agreement were a source of concern to potential investors. (Tr. 390-91.) On the other hand, John Addison—a business advisor affiliated with Dr. Law and his business entities—expressed concern to Dr. Law that accepting the 600,000 shares of Bioheart stock at \$1.80 per share rather than at the then prevailing price of \$8.00 per share would result in a substantial tax liability for the party accepting the stock, whether Dr. Law, CTI, or CTAL. (Ex. 28; see Tr. 380, 490, 556, 589-90.)

Consequently, the parties undertook discussions lasting from approximately February to July 2000 aimed at altering their original agreement. (See, e.g., Tr. 562; Exs. 37, 40, 42, 50.) These discussions included Dr. Law, Mr. Addison, and CTI's attorney, Anthony Pietrangelo. (Tr. 320-28, 336-38, 562-63; Ex. 40, 42, 189.) CTI's legal counsel played an active role in these negotiations. (See, e.g., Tr. 329-30; Ex. 42, 189.) Finally, on the morning of July 20, 2000, John Babbitt, Bioheart's Chief Financial Officer at the time, arrived in Memphis and met with Dr. Law. (Tr. 563-66; Ex. 214.) The two men continued to meet the next day. (Tr. 563-65.) Mr. Babbitt presented Dr. Law the Addendum, which had been put into its final form by Bioheart,

and on July 21, 2000, Dr. Law executed the Addendum (“Addendum”) amending the License Agreement.⁶ (Tr. 562-66; Ex. 22.) Dr. Law did not express that he was signing the Addendum against his will or under protest. (Tr. 109, 352-53, 564-65.)

The Addendum was signed by Dr. Law both in his individual capacity and in his capacity as Chairman and CEO of CTI. The Court summarizes the terms of the Addendum as follows:

- Section 1. Dr. Law and CTI agree to sign four separate agreements along with the Addendum: (a) a Scientific Advisory Board Consultation Agreement (“Advisory Board Agreement”); (b) a Supply Agreement (“Supply Agreement”) related to supplying cultured myoblasts; (c) an Inventions and Proprietary Rights Assignment and Confidentiality Agreement (“Inventions and Proprietary Rights Agreement”); and (d) a Warrant Certificate (“Warrant Certificate”) related to obtaining stock in Bioheart. This supersedes Section 10 of the License Agreement.
- Section 2(a). Superseding in its entirety Section 3 of the License Agreement, this subsection states, *inter alia*, that Dr. Law and/or CTI shall provide Bioheart with “all pertinent and critical information” needed to obtain FDA approval of an IND application for the processes being developed by Bioheart.
- Section 2(b). Bioheart agrees to grant CTI a five-year warrant exercisable for 1,200,000 shares of Bioheart stock at \$8.00 per share. This expressly supersedes Sections 4 and 5 of the License Agreement.
- Section 2(c). Bioheart agrees to make a \$3 million milestone payment to CTI upon commencement of a “bona fide Phase II human clinical trial study that utilizes technology claimed under [the ‘141 patent] with [FDA] approval in the United States[.]” This expressly supersedes Section 11 of the License Agreement.

⁶ The Court does not credit Dr. Law’s trial testimony that Mr. Babbitt arrived on the morning of July 21st and stated that his return flight was leaving early that afternoon. This rendition of facts directly contradicts testimony from Mr. Babbitt, which is corroborated by the copy of his airline ticket entered into evidence. (Tr. 563-66; Ex. 214.)

- Section 3. This supersedes Section 13 of the License Agreement and details a revised process for Bioheart to exercise a right of first refusal over intellectual property licenses to be granted by Dr. Law or CTI to any of Bioheart's competitors.

Along with the Addendum, Dr. Law executed the four other documents specified in Section 1. (Ex. 22.) Bioheart then provided the second \$500,000 payment. Evidence presented at trial indicated that this money went, at least in part, to fund scholarly articles by Dr. Law and to fund Dr. Law's development of new patents. (Tr. 347-49; see Tr. 536-37.) Dr. Law did not directly share his articles or research with Bioheart specifically, although his articles were generally available due to their publication. (Tr. 348-49.) There was also evidence, which the Court credits, that Dr. Law utilized at least part of Bioheart's second \$500,000 payment to support animal experimentation that he conducted in Singapore for Bioheart's benefit. (Tr. 838.)

E. Subsequent Relations Between Plaintiffs and Bioheart

In the period following execution of the Addendum, Bioheart was still preparing for the filing of its initial IND application with the FDA, but Dr. Law's operations in Memphis were already the subject of an ongoing FDA investigation into his practices. The parties had entered into the Supply Agreement on the premise that CTI would be Bioheart's primary, if not sole, supplier of cultured myoblast, but CTI was never able to perform the Supply Agreement in spite of Bioheart's repeated insistence that its performance was needed. (See, e.g., Tr. 310-14, 516-17, 581, 670, 720; Ex. 99.) Ultimately, Bioheart began seeking other suppliers, which had the effect of delaying its IND application. (Tr. 582.)

As indicated above, Section 2(a) of the Addendum obligated Dr. Law and/or CTI to provide Bioheart with "all pertinent and critical information" needed "to file an IND with the FDA and to have [the IND application] approved by the FDA." (Ex. 22.) Providing this information was a vital part of facilitating Bioheart's submission of an IND application. (Ex. 66.) Dr. Law, however, never discharged this obligation as Bioheart had envisioned. (Tr. 574; see Tr. 427, 429, 734.) Dr. Law failed to provide Bioheart with his complete standard operating procedures ("SOP's") for culturing myoblasts even though Bioheart needed them in order to file

its IND application, and the SOP's Dr. Law did provide were either redacted or so vague as to be unhelpful. (Tr. 598-99, 720-22, 767, 788.) Declaring it to be proprietary information, Dr. Law also withheld information from Bioheart regarding the formulation of the culturing media employed in his processes, which was likewise required for the IND application. (Tr. 674-77, 721-22.) Similarly, Dr. Law never gave Bioheart all the information needed regarding the source of his media's ingredients, nor did he ever furnish the necessary certificates of analysis for these ingredients. (Tr. 709, 720-21, 723, 725.) Although Bioheart requested it, Dr. Law and CTI also refused Bioheart even limited access to their "drug master file"⁷ in relation to certifying the safety of Dr. Law's cell culturing media. (Tr. 292-93, 676-77.) Additionally, Dr. Law did not make available to Bioheart information on shipping and transporting cultured myoblasts. (Tr. 680, 726.)

Determining that Dr. Law's SOP's did not comply with the FDA's cGMP standards and facing a lack of necessary information about Dr. Law's processes and media,⁸ Bioheart elected to develop its own SOP's and culturing media rather than rely upon Dr. Law and CTI. (Tr. 429-30, 681-82, 723, 732-33, 788.) Dr. Law insisted at trial that he only withheld the SOP's for yielding the billions of cells that he would produce in MTT because that number of cells would be too great for Bioheart's needs. (Tr. 839-40.) The Court finds, however, that Dr. Law's failure to provide information was not as harmless as he contends.⁹

After developing its own SOP's and culturing media, Bioheart filed an IND application in 2002. (Tr. 438-39, 695, 723, 788.) Bioheart also built a cGMP-compliant cell culturing facility. (Tr. 635, 805.) Subsequent attempts to consult with Dr. Law did not result in meaningful assistance, and Dr. Law continued to withhold information. (Tr. 782-83, 785-87; Ex. 125.) At

⁷ A "drug master file" contains information that can be critical to verifying the safety of a product like Dr. Law's culturing media. (Tr. 676.) The evidence indicated that it would have been possible to grant the FDA access to his drug master file without giving that information to Bioheart directly, thus protecting confidentiality. (*Id.*)

⁸ The term "cGMP" refers to "current good manufacturing practice," which is the standard of compliance set by the FDA. (*See* Tr. 87, 425.) *See* 21 U.S.C. § 351(a)(2)(B).

⁹ After the Addendum, Bioheart also continued to encounter difficulty in obtaining a research license from Dr. Law for Duke University—the license was necessary in order for Bioheart to receive information from Duke which Bioheart needed for its IND application. (Ex. 60.)

trial, Bioheart submitted that Dr. Law's failures severely hindered its IND application and forced it to develop SOP's and culturing media at a cost of \$3,737,657.19. (Ex. 182.)

MyoCell now depends upon processes and media that differ substantially in several significant ways from those developed by Dr. Law.¹⁰ (Tr. 788, 792-805.) Bioheart's first trial of MyoCell in the United States occurred in April 2003. (Tr. 439.) The next significant step in the development process, FDA-approved Phase II/III human clinical trials, commenced in October 2007. No commercialization of MyoCell has yet occurred, although Bioheart has received partial reimbursement of certain expenses in relation to its clinical trials. (Tr. 641.) Bioheart has generated revenue from sales of its MyoCath catheter, but the proof at trial established that this device is based upon another patent—the Schmidt catheter patent—and not upon Dr. Law's technology or research. (Tr. 643; Ex. 146.)

F. Bioheart's Operations in Korea

In 2006, Bioheart, along with Bioheart Florida, LLC,¹¹ started an endeavor with two Korean companies—Bioheart Korea, Inc. ("BHK") and Bioheart Manufacturing, Inc. ("BHM")—with the goal of enabling BHM to provide myoblast therapy products in Asia. (Tr. 449-51; Exs. 140, 141, 205.) As part of this venture, Bioheart received stock in BHM valued at over ₩3 billion. (Tr. 451; Exs. 140, 141.) In return, Bioheart agreed to supply certain technologies and to train Korean laborers in tasks related to myoblast therapy. (Tr. 541.) To protect Bioheart's intellectual property and trade secrets, Bioheart has imposed several requirements. (Tr. 501-03, 543-44.) These include limiting the Korean facility's receipt of biopsies to those approved by Bioheart and requiring employees at the facility to sign an agreement protecting Bioheart's trade secrets. (Tr. 543-44.) Bioheart also does not reveal to the Korean facility the content of the culturing media Bioheart sends it. (*Id.*) This arrangement does not involve any licensing or sublicensing of intellectual property. (Tr. 502, 541-42.) After the

¹⁰ Some testimony from Kristin Comella, a scientist employed at Bioheart, was received in closed proceedings as she was required to detail many of Bioheart's trade secrets related to MyoCell. (Tr. 788-825.) The Court credits Ms. Comella's testimony and finds that it revealed many ways in which MyoCell does not rely on Dr. Law's technology, processes, or teachings.

¹¹ Bioheart's precise relationship to Bioheart Florida, LLC was never made clear to the Court.

filing of this lawsuit, Bioheart, Bioheart Florida, LLC, BHK, and BHM entered into an agreement clarifying that Bioheart had not purported to furnish a license to utilize the ‘141 patent or any other patents or know-how granted to Bioheart by Dr. Law or his affiliated entities. (Exs. 205, 213.)

II. CONCLUSIONS OF LAW¹²

A. Plaintiffs’ Standing to Sue

Bioheart raises a challenge to Plaintiffs’ standing to maintain this suit, and it is this argument that the Court must first address. Bioheart states that because the License Agreement was signed by Mr. Leonhardt as Chairman and CEO of Bioheart and by Dr. Law as Chairman and CEO of CTI, the only proper parties to that contract are Bioheart and CTI. Thus, Bioheart contends, Plaintiffs cannot sue under the License Agreement as they lack standing to enforce its provisions. Similarly, although Bioheart concedes that Dr. Law is arguably a party to the Addendum because Dr. Law signed it both in his individual capacity and in his capacity as Chairman and CEO of CTI, Bioheart maintains that Plaintiffs lack standing under the Addendum as well because in this case Plaintiffs seek to enforce rights and benefits conferred by the Addendum on CTI alone.¹³

The Court agrees with Bioheart that the only two parties to the License Agreement are Bioheart and CTI. The Court further finds that the parties to the Addendum are Bioheart, CTI, and Dr. Law. Given that Dr. Law signed the Addendum in his individual capacity and that he is specifically assigned rights and duties in the Addendum, it would be peculiar to find that he is not a party to it.¹⁴ Being a party to the Addendum, Dr. Law may sue to enforce it, though he cannot personally claim entitlement to the milestone payment under the Addendum since it is

¹² The parties agree that Tennessee substantive law governs all claims and counterclaims in this case.

¹³ Dr. Law conceded in his testimony that CTI never assigned to himself or CTAL any legal claims CTI might have against Bioheart. (Tr. 276.) Furthermore, there is no evidence that CTI ever assigned its rights under the License Agreement or Addendum to another party, such as CTAL.

¹⁴ The Court notes that the Addendum implies that Dr. Law had been a party to the License Agreement by stating, “This letter (“Addendum”) amends and supplements that certain full license agreement (“Agreement”) . . . dated February 7, 2000 between Bioheart, Inc. (“Bioheart or the “Company”), Dr. Peter Law and Cell Transplants International, LLC (“CTI”).” (Addendum, Preamble.) Irrespective of what this may be said to reveal about the License Agreement, it certainly evidences that Dr. Law was meant to be a party to the Addendum.

payable only to CTI. Cf. Restatement (Second) of Contracts § 305 cmt. a (1981) (“The promisee of a promise for the benefit of a beneficiary has the same right to performance as any other promisee[.]”); id. § 307 cmt. b (“Even though a contract creates a duty to a beneficiary, the promisee has a right to performance.”).

As Bioheart itself notes, Tennessee law allows certain persons to maintain legal actions in the name of an LLC after the LLC has been administratively dissolved. Tenn. Code Ann. § 48-245-1201 (“After an LLC has been terminated, any of its former managers, governors, or members may assert or defend, in the name of the LLC, any claim by or against the LLC.”); see Tenn. Code Ann. § 48-245-401(d).¹⁵ Dr. Law indisputably qualifies as one who can sue on CTI’s behalf. But Dr. Law has not filed suit in CTI’s name, and hence CTI is not properly before the Court. For the limited purpose of fully addressing the merits of Plaintiffs’ claims, however, the Court will assume *arguendo* that Plaintiffs’ action should be construed as seeking relief on behalf and for the benefit of the dissolved LLC, CTI.

Moreover, notwithstanding the fact that Bioheart and CTI are the only parties to the License Agreement, contrary to Bioheart’s position, the Court finds that Dr. Law and CTAL are intended third-party beneficiaries of certain of its terms. To qualify as a third-party beneficiary, Tennessee law requires the following:

- (1) The parties to the contract have not otherwise agreed;
- (2) Recognition of a right to performance in the beneficiary is appropriate to effectuate the intention of the parties; and
- (3) The terms of the contract or the circumstances surrounding performance indicate that either:
 - (a) the performance of the promise will satisfy an obligation or discharge a duty owed by the promisee to the beneficiary; or

¹⁵ Tennessee enacted the “Revised Limited Liability Company Act” in 2005, but the former act continues to govern an LLC created under the old law unless the LLC elects to be governed by the new act. See Tenn. Code Ann. § 48-249-1002(a)(B). Thus, CTI is governed by the former act. Of course, the revised act likewise allows specified individuals to pursue claims in the name of an LLC after its dissolution. See Tenn. Code Ann. § 48-249-622.

(b) the promisee intends to give the beneficiary the benefit of the promised performance.

Owner-Operator Indep. Drivers Ass'n v. Concord EFS, Inc., 59 S.W.3d 63, 70 (Tenn. 2001) (adopting position of Restatement (Second) of Contracts); see Benton v. Vanderbilt Univ., 137 S.W.3d 614, 618 (Tenn. 2004). If not recognized as third-party beneficiaries, Dr. Law and CTAL would be left without the ability to avail themselves of the rights and benefits the contracting parties expressly manifested an intention to grant them—an odd result given that the License Agreement contains no language divesting third-party beneficiaries of the ability to sue.¹⁶ Therefore, the Court finds that although not parties to the License Agreement, Dr. Law and CTAL have standing as third-party beneficiaries to sue for enforcement of those terms which were meant to benefit them.¹⁷

Finally, Plaintiffs attempt to show that CTAL necessarily must also be a party to these agreements because, they say, CTAL is a holding company for all of Dr. Law's intellectual property rights. As support for this contention, Plaintiffs presented a document purportedly executed on August 8, 1996 and assigning all of Dr. Law's individual property rights—whether past, present, or future—to CTAL. (Ex. 192.) Dr. Law signed the document both in his individual capacity and as the representative of CTAL. According to Plaintiffs, this assignment thereafter gave CTAL alone the right to license his intellectual property, including the '141 patent. (Tr. 264.) The assignment is not notarized and was never recorded with the Patent & Trademark Office.¹⁸ (Ex. 192; Tr. 266.). No one witnessed Dr. Law's signing of this document. (Tr. 266.) When cross-examined at trial, Dr. Law denied that he had generated this document for

¹⁶ CTAL is not mentioned in the Addendum, either explicitly or by necessary implication, but Dr. Law is a party to the Addendum. Accordingly, it is not necessary to analyze the Addendum for third-party beneficiaries.

¹⁷ Absent an express provision in the contract, contracting parties retain the power to alter duties to a third-party beneficiary unless, before receiving notification of the modification, the third-party beneficiary "materially changes his position in justifiable reliance on the promise or brings suit on it or manifests assent to it at the request of the promisor or promisee." Restatement of Contracts (Second) § 311(3). As will be seen, it is a moot question whether any third-party beneficiary rights vested prior to the signing of the Addendum because the Court finds that the Addendum is valid and enforceable and that Dr. Law was a party to the Addendum. This has the effect of leaving only CTAL in the position of potentially arguing that a prior vesting of its rights under the License Agreement precluded the subsequent modification of its benefits under License Agreement. CTAL, however, has never advanced such an argument.

¹⁸ Interestingly, an assignment of rights to the '141 patent to Dr. Law from his former assistant, Tena Goodwin, on August 19, 1996 was duly recorded with the Patent & Trademark Office. (Tr. 265.)

purposes of this litigation rather than in 1996, but he then offered no satisfactory reason for his failure to record it with the Patent & Trademark Office. (Tr. 267.)

The Court cannot accept Dr. Law's assertion that he assigned his intellectual property rights to CTAL in 1996 as such an assignment would be too inconsistent with other uncontroverted evidence in this case. For example, in 2000, when Dr. Law sought a legal opinion on behalf of CTRF from the law firm of Moore & Van Allen, PLLC as to ownership of the '141 patent, he never informed that firm of this purported prior assignment. (Tr. 267-74; see Ex. 24.) Dr. Law's explanation for this—essentially that he must simply have neglected to tell his attorneys about the assignment—is likewise not credible. Had there truly been an assignment to CTAL in 1996, as Plaintiffs now claim, the Court believes that Dr. Law more likely than not would have ensued that Moore & Van Allen was made aware of that fact. Furthermore, CTI has frequently held itself out as the holder of the rights to the '141 patent both to the public generally and in representations to Bioheart. (Exs. 34, 215.) It is not unexpected then that the license for the '141 patent granted to Duke University for Dr. Taylor's research was conferred by CTI, and in this license CTI represented that it was the owner of the '141 patent. (Ex. 196 at Ex. 15.) The Court accordingly cannot credit Plaintiffs' assertion that CTAL was the holder of Dr. Law's intellectual property rights at the time the License Agreement and Addendum were executed.

B. Enforceability of the Addendum

Next, the Court must address the enforceability of the Addendum signed by Dr. Law and Bioheart on July 21, 2000. Plaintiffs do not dispute that Dr. Law signed the Addendum both individually and as Chairman and CEO of CTI, but they contend that the Addendum is unenforceable because it lacked consideration and was the product of economic duress.

1. Want of Consideration

Plaintiffs first argue that the Addendum is a *nudum pactum* because it placed upon Bioheart no obligation that was not already imposed upon it by the License Agreement and it afforded Plaintiffs—or more properly speaking, Dr. Law and CTI—no new benefits. Bioheart responds by noting several provisions of the Addendum that it says show meaningful changes to

previously agreed to obligations between the parties, including changes that were designed to benefit Dr. Law and CTI.

A contract modifying a prior contract must be supported by new consideration. Givens v. Mullikin ex rel. Estate of McElwaney, 75 S.W.3d 383, 406 (Tenn. 2002). “Consideration may be either a benefit to the promisor or a detriment to or obligation upon the promisee.” Bratton v. Bratton, 136 S.W.3d 595, 602 (Tenn. 2004) (citations omitted); see Brown Oil Co., Inc. v. Johnson, 689 S.W.2d 149, 151 (Tenn. 1985). Consideration may also take the form of mutual promises. Bratton, 136 S.W.3d at 602 (citations omitted); see generally Restatement (Second) of Contracts §§ 71-72. In Tennessee by statute, “[a]ll contracts in writing signed by the party to be bound, or the party’s authorized agent and attorney, are prima facie evidence of a consideration.” Tenn. Code Ann. § 47-50-103. The party asserting a lack of consideration bears the burden of overcoming this presumption. Pyburn v. Bill Heard Chevrolet, 63 S.W.3d 351, 358 (Tenn. Ct. App. 2001) (citing Atkins v. Kirkpatrick, 823 S.W.2d 547, 552 (Tenn. Ct. App. 1991)).

The Court rejects Plaintiffs’ argument that the Addendum lacked consideration. The evidence at trial showed that soon after the License Agreement had been entered into all parties had concerns about its terms. Importantly, Mr. Addison was troubled by the potential tax liability that would have resulted if Plaintiffs had availed themselves of the provision of the License Agreement allowing Dr. Law, CTI, or CTAL to obtain Bioheart stock at \$1.80 per share rather than at \$8.00 per share, the prevailing price at the time. The Addendum addressed this problem by raising the price per share to \$8.00 and replacing the immediate right to purchase 600,000 shares of Bioheart stock with a five-year warrant exercisable for 1,200,000 shares.¹⁹

¹⁹ At trial, Plaintiffs took the position that the License Agreement did not obligate CTI to purchase any Bioheart stock and that it created an option of unlimited duration. Bioheart argued otherwise. While the Court need not decide whether the License Agreement compelled Plaintiffs or CTI to purchase Bioheart stock, the Court reads Section 4 of the License Agreement as plainly contemplating an immediate purchase of shares and thus rejects Plaintiffs’ argument that the option it created was of unlimited duration. Similarly, the Court agrees with Bioheart’s position that the purchaser of the stock—whether it was to be CTI, CTAL, or Dr. Law—would have been required by Section 4 to pay \$1.80 per share. Plaintiffs’ argument to the contrary would inexplicably read the price term out of the License Agreement altogether. It would also leave unexplained why it was necessary for Section 5 of the License Agreement to give CTI, CTAL, or Dr. Law an option to acquire an additional 600,000 shares within thirty days. If the stocks did not need to be paid for, presumably CTI, CTAL, or Dr. Law would have simply requested them shortly after signing the License Agreement.

Bioheart's agreeing to cap at \$8.00 per share the price CTI would pay enabled CTI to lock in the price at \$8.00 per share and thereby take advantage of any subsequent increases in the value of Bioheart's stock without having to make an immediate purchase.

These changes alone regarding the purchase of stock confer a benefit sufficient to constitute consideration. Although Bioheart already had a duty under the License Agreement to make stock available to CTI or Plaintiffs, the Addendum altered this obligation in a way that benefited CTI. Cf. Restatement (Second) of Contracts § 73 (noting that performance of an existing legal duty may be consideration where it differs from the duty owed in more than a superficial way). Therefore, the Court concludes that Plaintiffs have not established a lack of consideration rendering the Addendum unenforceable.

2. Economic Duress

Plaintiffs also argue that the Addendum is voidable because it resulted from economic duress. They contend that Bioheart breached the License Agreement by not making the second \$500,000 payment within the ninety days set forth in the License Agreement and that this had devastating effects on Plaintiffs' financial condition. Because of these adverse economic conditions, Plaintiffs say, Dr. Law and CTI were forced to accept the Addendum in July 2000 because it was their only means of obtaining the \$500,000 already owed. Bioheart responds by arguing that it was not responsible for these claimed financial problems and that the Addendum was the product of extensive negotiations over several months prior to execution of the agreement.

Economic duress, also known as business compulsion, is firmly rooted in Tennessee law as a defense to enforcement of a contract. See Johnson v. Ford, 245 S.W. 531, 540-41 (Tenn. 1922); see generally Stephen W. Feldman, 21 Tenn. Practice: Contract Law and Practice § 6:6 (2008). "Economic duress has been defined as 'imposition, oppression, undue influence, or the taking of undue advantage of the business or financial stress or extreme necessities or weakness of another[.]'" Cumberland & Ohio Co. of Texas, Inc. v. First Am. Nat'l Bank, 936 F.2d 846, 850 (6th Cir. 1991) (quoting Crocker v. Schneider, 683 S.W.2d 335, 338 (Tenn. Ct. App. 1984)).

To prove economic duress the victim must show that there existed an improper and wrongful external influence sufficient “to overcome the mind and will of a person of ordinary fitness.” FDIC v. Ramsey, 612 F. Supp. 326, 328 (E.D. Tenn. 1985) (citing Fogg v. Union Bank, 63 Tenn. 530, 535 (1830)); see Boote v. Shivers, 198 S.W.3d 732, 745 (Tenn. Ct. App. 2005) (“Duress consists of unlawful restraint, intimidation, or compulsion that is so severe that it overcomes the mind or will of ordinary persons.”) (citations omitted). A threat to breach a contract is, standing alone, not sufficient to constitute duress. 28 Richard A. Lord, Williston on Contracts § 71:41 (4th ed. Supp. 2008) [hereinafter, “Williston”]; see generally Restatement (Second) of Contracts § 176, cmt. e (discussing circumstances under which threat to breach does not render modification of contract improper). Whether a party’s assent was obtained by duress is a fact-intensive inquiry, driven by the particular circumstances present in each case. Rainey v. Rainey, 795 S.W.2d 139, 147 (Tenn. Ct. App. 1990) (citations omitted). The ability to rely upon the defense of duress may be waived if a party fails to promptly seek avoidance of the contract. Cumberland & Ohio Co., 936 F.2d at 850 (citing DiRose v. PK Mgmt. Corp., 691 F.2d 628, 633-34 (2d Cir. 1982)); Loud v. Hamilton, 51 S.W. 140, 146-47 (Tenn. Ch. App. 1898) (citation omitted). Under Tennessee law, a party seeking to rely upon economic duress must establish this defense by clear and convincing evidence. Exum v. Washington Fire & Marine Ins. Co., 297 S.W.2d 805, 809 (Tenn. Ct. App. 1955).

The Court finds that Plaintiffs have failed to prove economic duress by a preponderance of the evidence, let alone by clear and convincing evidence. The financial problems faced by Dr. Law and CTI at the time of the Addendum’s signing were independently caused by CTI’s own inability to comply with FDA standards—something over which Bioheart had no control. Moman v. Walden, 719 S.W.2d 531, 534 (Tenn. Ct. App. 1986) (“The pressure of financial circumstances is insufficient to establish economic duress which will allow a party to avoid an agreement when the other party to the agreement is not responsible for the financial circumstances of the party.”); see Holloway v. Evers, No. M2006-01644-COA-R3-CV, 2007 WL 4322128, at *9 (Tenn. Ct. App. Dec. 6, 2007) (noting that party’s health and financial problems

“were not caused by the defendants” and “many people are required to make business and other decisions while facing such problems”). This is particularly true inasmuch as the \$500,000 that Plaintiffs say Bioheart was wrongfully withholding was, under the terms of the License Agreement, not an outright payment for use as the payee might wish. Rather, it could only be used to fund “research of mutual interest” by CTI/CTAL. Thus, the Court finds that Bioheart’s failure to pay the \$500,000 to fund research of mutual interest within ninety days of the License Agreement’s execution was not the cause of the financial difficulties faced by Dr. Law or CTI.²⁰

This was a transaction among sophisticated actors, and, contrary to the characterization suggested by Plaintiffs, the evidence shows that the Addendum was hardly sprung upon Dr. Law without notice. Prior to the day that Mr. Babbitt arrived in Memphis with documents for Dr. Law’s signature, the parties had over a period of several months engaged in detailed negotiations, exchanging drafts and discussing potential terms. See, e.g., Kinnard v. Shoney’s, Inc., 100 F. Supp. 2d 781, 792 (M.D. Tenn. 2000) (considering fact that complaining party had considered over many months whether to sign contract). Dr. Law, an exceptionally intelligent and highly educated individual, had access to legal and business advisors prior to executing the Addendum. At trial, Dr. Law testified that he even called his lawyer for advice while meeting with Mr. Babbitt on July 21, 2000, but when his lawyer said he was not able to come at that time, Dr. Law elected to deal with Mr. Babbitt on his own. (Tr. 111-12.) The Court finds no credible evidence that Bioheart ever exerted undue pressure on Plaintiffs to compel Dr. Law and CTI to agree to the Addendum, and Bioheart certainly exerted no pressure sufficient to overcome the mind and will of an ordinary person. The fact that Bioheart very much wanted the Addendum and the other associated agreements does not itself constitute undue pressure. Furthermore, if CTI or CTAL felt in July of 2000 that Bioheart was wrongfully withholding money due, then there was always the option of refusing the Addendum and suing for the payment Bioheart owed. See Restatement (Second) of Contracts § 175, cmt. b (“A threat, even if improper, does not

²⁰ The fact that Bioheart had not issued CTI, CTAL, or Dr. Law stock under Sections 4 and 5 of the License Agreement is also no basis for claiming economic duress. As discussed above, this stock had to be purchased, albeit at a reduced price, and neither Dr. Law nor CTI ever acted to undertake such a purchase.

amount to duress if the victim has a reasonable alternative to succumbing and fails to take advantage of it.”). Instead, Dr. Law and CTI accepted the Addendum along with the other accompanying agreements without ever uttering any hint of protest until they decided that they preferred the License Agreement without the Addendum’s changes. (Tr. 353.)

Plaintiffs rely heavily on an opinion from the Tennessee Court of Appeals, Duffy Tool & Stamping, Inc. v. Bosch Automotive Motor Systems Corp., No. M1997-00144-COA-R3-CV, 2000 WL 122225 (Tenn. Ct. App. Feb. 1, 2000). The facts of that case, however, are markedly different from those presented here. In Duffy Tool, a supplier of automotive parts engaged in a blatant anticipatory repudiation of a contract with a manufacturer by announcing that it would cease all future shipments in six weeks even though more than two years remained on their original contract. Id. at *1-2. The supplier’s breach threatened to disrupt the manufacturer’s entire ability to supply its customer, a Ford plant, which would have in turn shut down that plant’s operations. Id. at *6. Against this backdrop, the supplier then exacted a modified contract from the manufacturer, which altered the supplier’s obligations during the period in which it was “winding down” as the manufacturer’s supplier. Id. at *4. The supplier later sued the manufacturer for breach of this latter agreement. Id. at *2. The Court of Appeals held that the modification was the product of economic duress and thus voidable. Id. at *6.

Nothing about the decision in Duffy Tool is at odds with finding an absence of economic duress in the instant case. In Duffy Tool, the party demanding the concessions was the cause of the threatened economic peril, whereas here—as already discussed—the financial difficulties cited by Plaintiffs were not the result of any conduct properly attributable to Bioheart. Duffy Tool also involved a clear repudiation of a prior contract, but Bioheart never clearly repudiated the License Agreement prior to the signing of the Addendum. Accordingly, the Court concludes that Plaintiffs have failed to satisfactorily demonstrate that the Addendum is unenforceable due to economic duress.

3. Effect of Finding Addendum Enforceable

Because the Court concludes that the Addendum is valid and enforceable, the Court finds for Bioheart on the first three claims of Plaintiffs' amended complaint. Count One of their amended complaint, which seeks a declaratory judgment declaring the Addendum invalid and unenforceable is thus dismissed. Likewise, the Court dismisses Counts Two and Three of the amended complaint related to obtaining Bioheart stock under the License Agreement. Furthermore, the Court finds for Bioheart on its counterclaim asking for a declaratory judgment as to the Addendum.

C. Plaintiffs' Claim for the \$3 Million Milestone Payment

In Count Four of their amended complaint Plaintiffs sue for damages under Section 11 of the License Agreement, the provision obligating Bioheart to make a \$3 million milestone payment to CTI/CTAL upon the occurrence of certain events. Section 2(c) of the Addendum contains language superseding Section 11 of the License Agreement. Because the Court has found that the Addendum validly supplants parts of the License Agreement, any claim to the milestone payment under the terms of License Agreement is moot. Nevertheless, Plaintiffs contend that they are also entitled to the milestone payment under the Addendum because the conditions described in Section 2(c) of the Addendum have now occurred. Specifically, Plaintiffs argue that Bioheart has commenced a bona fide Phase II human clinical trial study in the United States utilizing technology claimed under the '141 patent with FDA approval. Bioheart makes several independent arguments in response. The Court concludes that Bioheart is entitled to judgment on Count Four of Plaintiffs' amended complaint.

1. Lack of Standing

First, Bioheart notes that the Addendum confers the right to receive the milestone payment not on CTAL or Dr. Law, but on CTI alone. As such, Bioheart contests Plaintiffs' standing to sue for the milestone payment under the Addendum. As discussed above, however, the Court finds that Dr. Law was a party to the Addendum and, therefore, he has standing to sue

for its enforcement, notwithstanding the fact that he can legitimately assert no personal entitlement to the money.

2. Existence and Satisfaction of Condition Precedent

Bioheart's second argument is that the milestone payment under Section 2(c) is subject to a condition precedent which neither Dr. Law nor CTI has satisfied. According to Bioheart's interpretation, Section 2 of the Addendum creates a condition precedent when it prefaces the terms of the new agreement with a recital stating that the contract is "[i]n consideration of Dr. Law's and CTI's execution, delivery *and performance* of the above-identified agreements [i.e., the Advisory Board Agreement, Supply Agreement, Inventions and Proprietary Rights Agreement, and Warrant Certificate] as well as the [License] Agreement, as amended and supplemented hereby[.]" (Addendum § 2 (emphasis added).) In the provisions that followed, Bioheart agreed, among other things, to make the milestone payment upon "commencement of a bona fide Phase II human clinical trial study that utilizes technology claimed under [the '141 patent] with [FDA] approval in the United States." (Addendum § 2(c).) Bioheart now cites four ways in which, it says, the condition precedent has not been satisfied: (1) CTI never performed and never was able to perform the Supply Agreement under which CTI was to furnish Bioheart with FDA-quality myoblasts; (2) Dr. Law failed to comply with his obligation under the Inventions and Proprietary Rights Agreement to give Bioheart access to his information—including his formulae, processes, manufacturing techniques, and trade secrets—related to heart muscle regeneration and angiogenesis; (3) Dr. Law did not conduct research of "mutual interest" in exchange for receiving the \$500,000 payment; and (4) Dr. Law did not provide Bioheart "with all pertinent and critical information in order to file an IND with the FDA and to have it approved by the FDA" as he was obligated to do by Section 2(a) of the Addendum. Plaintiffs' principal argument in response is that these are not part of a condition precedent to the milestone payment. Rather, they urge that the only condition to payment of the milestone is Bioheart's initiation of the Phase II human clinical study, an event that has occurred.

“A condition precedent generally is defined as ‘an act or event, other than a lapse of time, which must exist or occur before a duty of immediate performance of a promise arises.’” Summit Petroleum Corp. of Indiana v. Ingersoll-Rand Fin. Corp., 909 F.2d 862, 866 (6th Cir. 1990) (quoting J. Calamari & J. Perillo, The Law of Contracts § 11-3, at 384 (2d ed. 1977)). A condition precedent may be a prerequisite to the coming into existence of a binding contract, or it may be what causes a duty in an existing contract to arise. Strickland v. City of Lawrenceburg, 611 S.W.2d 832, 837 (Tenn. Ct. App. 1980) (citation omitted). If it is subject to a condition precedent, a duty need not be performed until the condition occurs or the nonoccurrence of the condition is excused. Holland v. Holland, No. M1999-02791-COA-R3-C, 2001 WL 585107, at *3 (Tenn. Ct. App. June 1, 2001) (citations omitted).

Plaintiffs correctly note that Tennessee law, like the law in other jurisdictions, does not favor contractual conditions precedent. See, e.g., Koch v. Construction Tech., Inc., 924 S.W.2d 68, 71 (Tenn. 1996) (citation omitted); 13 Williston, *supra*, § 38:13 (“Contract conditions are disfavored, and will not be found in the absence of unambiguous language indicating an intention to create a conditional obligation.”). Generally, where it is fairly debatable whether particular language in a contract creates a condition precedent, the language will be interpreted in favor of creating only a covenant or promise. Harlan v. Hardaway, 796 S.W.2d 953, 957-58 (Tenn. Ct. App. 1990) (citations omitted). Where, however, it is the parties’ intention, as gleaned from the language of the contract and the surrounding circumstances, to create a condition precedent, it will be upheld. See, e.g., Miller v. Resha, 820 S.W.2d 357, 360 (Tenn. 1991) (citing Harlan, 796 S.W.2d at 957-58); cf. Vantage Tech., LLC v. Cross, 17 S.W.3d 637, 650 (Tenn. Ct. App. 1999) (“The goal of contract interpretation is to ascertain the intent of the parties according to the usual, natural, and ordinary meaning of the words used by the parties.”) (citation omitted). Although it does not require the use of any particular language, “[t]he presence of a condition is usually signaled by a conditional word or phrase such as ‘if,’ ‘provided that,’ ‘when,’ ‘after,’ ‘as soon as,’ and ‘subject to.’” Harlan, 796 S.W.2d at 958 (citations omitted).

Considering the Addendum as a whole, the Court concludes that the preface in Section 2 does not create a condition precedent to the \$3 million milestone payment. First, Section 2 does not employ any of the terms or phrases usually associated with creation of a condition precedent. See Harlan, 796 S.W.2d at 958. While the specific language of Section 2(c) does signal a condition by making Bioheart’s payment due only “upon commencement” of a Phase II human clinical study “utilizing technology claimed” under the ‘141 patent, no reference is made within Section 2(c) to any other condition. And, as Plaintiffs note, in Section 1 of the Addendum, the parties indisputably set up a condition precedent to the Addendum’s becoming an enforceable contract. There the Addendum reads, “It shall be an *express condition precedent* to the effectiveness of this Addendum that . . . [the four described agreements] . . . be executed and delivered by the parties hereto.” (Addendum § 1 (emphasis added).) Thus, Section 1 is compelling evidence to indicate that, when these parties unmistakably intended a condition precedent, they knew how to express their wish clearly. Presumably then, if the parties had intended Section 2 to also contain a condition precedent, they would have been just as explicit. See Mackinder v. Schawk, Inc., No. 00 Civ. 6098(DAB), 2005 WL 1832385, at *6 (S.D.N.Y. Aug. 2, 2005) (citing Int’l Fid. Ins. Co. v. Rockland, 98 F. Supp. 2d 400, 412 (S.D.N.Y. 2000) (“Sophisticated lawyers, such as those drafting standard forms . . . must be presumed to know how to use parallel construction and identical wording to impart identical meaning when they intend to do so, and how to use different words and construction to establish distinctions in meaning.”)). Furthermore, Bioheart’s argument puts too great an emphasis on use in Section 2 of the word “performance”—a term whose inclusion can fairly well be characterized as referring to the mutual promises (detailed in the subparts to Section 2) which serve as the Addendum’s consideration.²¹ Taking all of these factors along with the legal presumption against finding conditions precedent, the Court finds that Bioheart’s \$3 million milestone payment is not subject to a condition precedent other than commencement of the clinical study described in Section

²¹ To the extent there is ambiguity in the Addendum it must of course be construed against Bioheart since it was the ultimate drafter of the agreement. See Spiegel v. Thomas, Mann & Smith, P.C., 811 S.W.2d 528, 531 (Tenn. 1991) (citation omitted).

2(c). A party's failure to perform the duties Bioheart references could constitute a breach and be the basis of an independent claim for damages, but it would not amount to a failure of a condition precedent.

3. Failure of Consideration

Bioheart's post-trial filings also suggest that the \$3 million milestone payment is not due because Dr. Law has not followed through on all of his obligations under the Addendum, which would amount to a failure of consideration. A "failure of consideration" refers to an uncured material failure by one party to perform its promised obligations under a contract. See Converse v. Zinke, 635 P.2d 882, 887 (Colo. 1981). "If one party has failed to perform the bargained for exchange, the other party may be relieved of a duty to continue its own performance, where the failure is material and unexcused." Id.; see 14 Williston, *supra*, § 43:5. A failure of consideration means that the contract, although once valid, ceases to be enforceable. See, e.g., Aquagen Int'l, Inc. v. Calrae Trust, 972 P.2d 411, 414 (Utah 1998) (citations omitted); First Nat'l Bank of Belfield v. Burich, 367 N.W.2d 148, 152 n.3 (N.D. 1985) (citations omitted); see generally 3 Williston, *supra*, § 7:11. This excuses the performance of the party which did not breach. See Converse, 635 P.2d at 887; Restatement (Second) of Contracts § 237.

As explained more fully below in discussing Bioheart's counterclaims, the Court concludes that Dr. Law did breach his duty under the Addendum to provide "all pertinent and critical information" necessary for Bioheart to file its IND application with the FDA. The Court, though, does not find that Dr. Law has totally failed to fulfill any of his obligations under the Addendum, nor did Bioheart seek to prove that he did. Dr. Law's breaches constitute no more than a partial failure of consideration, which can give rise to the remedy of rescission only if "the failure defeats the very object or purpose of the contract or renders that object impossible to accomplish."²² James Cable Partners, L.P. v. City of Jamestown, 818 S.W.2d 338, 345 (Tenn. Ct. App. 1991) (citing Farrell v. Third Nat'l Bank, 101 S.W.2d 158, 163 (Tenn. Ct. App. 1936)).

²² The Court agrees with Bioheart's observation that the Addendum is not a divisible or severable contract. See James Cable Partners, 818 S.W.2d at 344 (discussing "entire" versus "severable" contracts).

Given that Bioheart chooses to embrace the Addendum rather than to have the Addendum rescinded, Bioheart's remedy for Dr. Law's breach is to pursue a claim for money damages, not to have its own performance excused. See Converse, 635 P.2d at 887 (quoting A. Corbin, Corbin on Contracts, § 659 (1963)); see also James Cable Partners, 818 S.W.2d at 344 ("As a general rule, a contract can only be rescinded *in toto*. A contract can only be partially rescinded where the contract is severable."); cf. Chilton Ins. Co. v. Pate & Pate Enters., Inc., 930 S.W.2d 877, 887-88 (Tex. Ct. App. 1996) ("Treating a contract as continuing, after a breach, deprives the non-breaching party of any excuse for terminating their own performance.").

4. Utilization of Technology Claimed under the '141 Patent

Finally, Bioheart argues that the milestone payment is not due because MyoCell does not "utilize[] technology claimed under" the '141 patent. The Court agrees. CTI is entitled to no milestone payment if the Phase II human clinical study does not utilize technology claimed under the '141 patent, and the evidence at trial established that the MyoCell process does not. MyoCell is an autologous process, whereas the process described in '141 patent is allogenic. (Tr. 182-83, 737.) MyoCell also uses pure myoblasts, but the '141 patent describes the use of a mixture of myoblasts, myotubes, and young muscle fibers. (Tr. 281-82, 394-96; Ex.1.) Further, MyoCell utilizes a culturing media different from that developed by Dr. Law as well as a different method for storing and transferring cultured cells. (Tr. 792-805; Exs. 174-79.) In light of these substantial differences, the Court finds that Bioheart's MyoCell process does not utilize technology claimed under the '141 patent. The Court thus dismisses Count Four of Plaintiffs' amended complaint.

D. Plaintiffs' Royalty Claims on MyoCell and MyoCath

Plaintiffs also make claims for 5% royalties on "gross sales" of MyoCell pursuant to Section 6 of the License Agreement. They further argue that Bioheart has engaged in anticipatory repudiation of its obligation under Section 6 to pay royalties on "gross sales" of "products and services that read upon the claims" of Dr. Law's patents. Bioheart does not flatly assert that MyoCell does not read upon the claims of Dr. Law's patents. It contends instead that

MyoCell has not yet generated any “gross sales.” The Court agrees with Bioheart that the evidence at trial showed that Bioheart has only received some partial reimbursement of the costs of conducting clinical trials. (Tr. 641-43, 645-46; Ex. 181; see Tr. 279-80.) MyoCell has not yet been approved by the FDA for clinical use or otherwise been commercialized. The Court finds that “gross sales,” as that term is commonly understood, does not encompass these partial reimbursements. See Black’s Law Dictionary 1365 (8th ed. 2004) (defining “gross sales” as “[t]otal sales (esp. in retail) before deductions for returns and allowances”); see also id. at 1364 (giving relevant definition of “sale” as “[t]he transfer of property or title for a price”).

The Court also agrees with Bioheart that it has not engaged in anticipatory repudiation of its obligation to pay royalties on future gross sales. “In order to serve as an anticipatory breach of contract or repudiation, the words and conduct of the contracting party must amount to a total and unqualified refusal to perform the contract.” Wright v. Wright, 832 S.W.2d 542, 545 (Tenn. Ct. App. 1991) (citations omitted). There was no evidence that Bioheart has expressed, said, or done anything to totally and unqualifiedly repudiate an obligation to pay royalties should they become due.

Furthermore, the Court agrees with Bioheart that the proof at trial showed that its MyoCath technology, a catheter that Bioheart has commercialized, does not read upon Dr. Law’s patents. Rather, this technology is based upon an entirely different patent not associated with Plaintiffs. (Tr. 287, 643; Ex. 146.) Bioheart thus owes no royalties on any of its sales, and a failure to pay such royalties cannot constitute anticipatory repudiation. Accordingly, Plaintiffs’ claims under Counts Five and Six of their amended complaint are dismissed.

E. Plaintiffs’ Remaining Claims

Count Seven of Plaintiffs’ amended complaint seeks an accounting. “An accounting is an equitable remedy which allows the court to determine the extent of a misallocation of expenses and the damages resulting therefrom when there is fiduciary relationship between the parties.” In re Maxim Integrated Prods., Inc. Derivatives Litig., 574 F. Supp. 2d 1046, 1067 (N.D. Cal. 2008) (citing Carlson v. Hallinan, 925 A.2d 506, 538 n.211-12 (Del. Ch. 2006)); see William H.

Inman, Gibson's Suits in Chancery § 30.01 (8th ed. 2004) (stating that “an accounting is a species of disclosure” available only when legal remedies are inadequate to determine the amount owed by another). Generally, absent some duty at law to provide an accounting, an action in equity for an accounting requires a fiduciary relationship or some other special circumstance particularly meriting this remedy. See Rodgers v. Roulette Records, Inc., 677 F. Supp. 731, 738-39 (S.D.N.Y. 1988) (citations omitted). Bioheart correctly notes that there is no evidence indicating a fiduciary relationship between Plaintiffs and Bioheart or indicating that Bioheart has been entrusted with funds or other property for which an accounting might be warranted. To the extent that Plaintiffs’ request for an accounting was an effort to avail themselves of an historically available equitable remedy in actions for patent infringement, see Henry L. McClintock, Handbook on the Principles of Equity § 149 (2d ed. 1948); see, e.g., Gordon Form Lathe Co. v. Ford Motor Co., 133 F.2d 487 (6th Cir. 1943), Plaintiffs’ claims are dismissed because they have established no infringement by Bioheart. Count Seven is thus dismissed in its entirety.

Count Eight prays for damages from Bioheart for breach of the Licensing Agreement’s prohibition on sublicensing. Plaintiffs argue that Bioheart engaged in an improper sublicense of Dr. Law’s patents in relation to its operations in Korea. At trial, however, it was shown that Bioheart has taken great care to protect its and Dr. Law’s intellectual property in undertaking this Korean endeavor, and Bioheart’s relationship with BHK and BHM did not involve any licensing or sublicensing of Dr. Law’s intellectual property. The Court finds that Plaintiffs have not established that Bioheart has breached the License Agreement’s prohibition on sublicensing, and Count Eight is also dismissed.

Count Twelve seeks recovery under a theory of unjust enrichment. An action for unjust enrichment requires the conferring of a benefit upon another under conditions rendering retention of that benefit inequitable. Freeman Indus., LLC v. Eastman Chem. Co., 172 S.W.3d 512, 525 (Tenn. 2005) (citation omitted). Plaintiffs have made no showing of inequitable conduct or other wrongdoing by Bioheart leading to its being unjustly enriched. Nor have Plaintiffs shown an

inadequate remedy at law justifying equitable remedies, including recovery under a theory of unjust enrichment or for an implied or quasi-contract. To the contrary, Plaintiffs' claims at law fail and, there being a valid contract, they may not seek recourse in equity. See Metro. Gov't of Nashville & Davidson County v. Cigna Healthcare of Tennessee, Inc., 195 S.W.3d 28, 32 (Tenn. Ct. App. 2005) (stating that unjust enrichment is appropriate where "there is no contract between the parties or the contract has become unenforceable or invalid and the defendant will be unjustly enriched unless the court imposes an obligation") (citation omitted). Accordingly, this claim is dismissed.

Counts Nine and Ten have been dismissed by a prior order of the Court. (D.E. #31.) Count Eleven seeks to invoke the doctrine of equitable estoppel to toll the running of the statutes of limitations and repose on its claims. The Court has not dismissed any claims for a lack of timeliness. This count is now irrelevant and thus dismissed. The remaining counts of the amended complaint—Plaintiffs' claims for punitive damages and for injunctive relief—depend upon Plaintiffs' having proved that Bioheart breached its obligations in some way. As Plaintiffs have not demonstrated any such breach, these counts are dismissed as well.

F. Bioheart's Counterclaims

1. Declaratory Judgment

Bioheart's First Counterclaim requests a declaratory judgment regarding the validity of the Addendum signed by Dr. Law on July 21, 2000. As detailed above, Bioheart has demonstrated a real and substantial controversy of sufficient immediacy to merit declaratory relief as a means of effectively settling a dispute and clarifying the rights of the parties. See Scottsdale Ins. Co. v. Flowers, 513 F.3d 546, 554 (6th Cir. 2008) (considerations for issuance of declaratory judgment); Blakely v. United States, 276 F.3d 853, 872 (6th Cir. 2002); see also 28 U.S.C. §§ 2201-02. Therefore, the Court grants Bioheart's prayer for declaratory relief. The Court concludes and declares that the Addendum is a valid, legally enforceable agreement and that Sections 3, 4, 5, 10, 11, and 13 of License Agreement are duly superseded by the Addendum and no longer of legal force.

2. Bioheart's Claims Related to IND Process

Bioheart further argues that Dr. Law failed to satisfy his obligation under Section 2(a) of the Addendum to provide “all pertinent and critical information” necessary to file and have approved an IND application with the FDA and that as a result of this breach it has suffered damages totaling \$3,737,657.19. “The essential elements of any breach of contract claim include (1) the existence of an enforceable contract, (2) nonperformance amounting to a breach of the contract, and (3) damages caused by the breach of the contract.” ARC LifeMed, Inc. v. AMC-Tennessee, Inc., 183 S.W.3d 1, 26 (Tenn. Ct. App. 2005) (citations omitted). The evidence at trial clearly revealed that, for whatever reason, Dr. Law and CTI failed in numerous respects to provide information required for Bioheart’s filing of its IND application. Specifically, Dr. Law did not give Bioheart his complete SOP’s for culturing myoblasts, the formulation of the culturing media employed in his processes, or the full sourcing information for his media’s ingredients. (See Tr. 117, 292, 675-78, 680, 726, 767, 771, 784.) The result was that Bioheart could not rely upon Dr. Law and CTI in developing MyoCell and filing an IND application.

Although the Court finds that Dr. Law did materially breach Section 2(a), the Court does not find that Bioheart has established anything more than nominal damages.²³ The purpose of awarding damages in breach of contract cases is to put the party claiming a breach in as nearly the same position that it would have enjoyed had the other party performed. Wilhite v. Brownsville Concrete Co., Inc., 798 S.W.2d 772, 775 (Tenn. Ct. App. 1990) (citing Action Ads, Inc. v. William B. Tanner Co., Inc., 592 S.W.2d 572, 575 (Tenn. Ct. App. 1979)). A party can recover only nominal damages for a breach of contract unless the party proves actual injury. 24 Williston, supra, § 64:8; see Gay & Taylor, Inc. v. Am. Cas. Co., 381 S.W.2d 304, 307 (1963) (“Upon breach of a valid and binding contract, the law infers some damages, and generally the

²³ The Court finds no waiver of the breach because on several occasions after determining that Dr. Law was not fulfilling this term of the Addendum Bioheart communicated to him its desire for him to perform. See, e.g., 94th Aero Squadron of Memphis, Inc. v. Memphis-Shelby County Airport, 169 S.W.3d 627, 635-36 (Tenn. Ct. App. 2004) (citations omitted).

person guilty of the breach is liable for nominal damages, if actual damages cannot be proved.”) (citation omitted).

The evidence throughout trial of this case clearly indicated that the FDA would have been hostile to Dr. Law’s cell culturing media. Dr. Law’s use of fetal bovine serum and chick embryo extract were especially problematic in this regard, and these components would have presented serious, if not insurmountable, obstacles to obtaining FDA approval. (Tr. 679, 688-89; see Tr. 431, 436, 528-29.) While the FDA will allow some bovine media if it is shown to be from a qualified herd, Dr. Law’s use of chick embryo extract would likely have been unacceptable to the FDA.²⁴ (Tr. 434.) At trial, Bioheart did not demonstrate that Dr. Law’s media—particularly in light of his employing chick embryo extract—would have ultimately facilitated FDA approval of its IND application.

Even if Dr. Law had fulfilled his obligations, Bioheart would nonetheless likely have been compelled to try other options like those it ultimately pursued when Dr. Law was not forthcoming. The Court finds that neither Dr. Law nor CTI guaranteed in the License Agreement or Addendum that Dr. Law’s methods and media would prove to be acceptable to the FDA, and thus Dr. Law and CTI would not have been liable for any failure to gain the FDA’s approval.²⁵ As a result, Bioheart has not shown that it actually incurred more than nominal damages as a result of Dr. Law’s breach. Accordingly, the Court finds for Bioheart on the Second, Third, and Fifth Counterclaims of its countercomplaint, and awards Bioheart nominal damages against Dr. Law in the amount of \$1.00.²⁶

²⁴ As Mr. Leonhardt testified, Bioheart had real concerns about obtaining FDA approval in light of Bioheart’s planned reliance upon Dr. Law’s animal derived media, but Bioheart went forward anyway because “no other alternative was available[.]” (Tr. 528.)

²⁵ The reliance and restitutionary measures of damages would also be inappropriate inasmuch as Bioheart did not appear to expend sums specifically in reliance upon any representations by Dr. Law, and there is no risk here of unjust enrichment.

²⁶ Bioheart has not requested any relief other than money damages with respect to Dr. Law’s breach, nor does an equitable remedy obviously suggest itself.

3. Misappropriation

Bioheart further alleges that Dr. Law failed to conduct “research of mutual interest” in exchange for the second \$500,000 payment from Bioheart. Instead, it says, Dr. Law spent this \$500,000 to pursue his own new patents and publish articles, thereby misappropriating those funds. The Court first notes that the “mutual interest” qualification appears only in Section 3 of the License Agreement. But, Section 3 of the License Agreement is entirely superseded by Section 2(a) Addendum, which contains no language obviously restricting Dr. Law’s or CTI’s use of the \$500,000 to “research of mutual interest.” Indeed, Section 2(a) of the Addendum contains no obligation to conduct any kind of research. The only language referencing research is found in the first part of Section 2(a), which reads: “[T]he aggregate license/research and development fees payable by Bioheart under the first paragraph of Section 3 of the Agreement is a total sum of \$1,000,000 of which Dr. Law and CTI acknowledge that \$500,000 has been paid previously by Bioheart . . . The \$500,000 balance of said fees shall be paid upon execution of this contract.” (Addendum § 2(a).) The Court finds that this very general language only obliquely referencing research is not sufficient to restrict Dr. Law’s use of the second \$500,000 payment to “research of mutual interest.” Even assuming, however, that this language would suffice to restrict the uses to which this money could have been put, the Court finds that Dr. Law did conduct work on scholarly articles and development of other patents and that this qualifies as the type of research contemplated by the License Agreement as modified by the Addendum. The Court further credits Dr. Law’s rebuttal testimony that he also conducted some of the animal experimentation that Bioheart says it had intended Dr. Law to perform with this money. (Tr. 838.) Therefore, Bioheart has not proven a misappropriation, and this counterclaim is dismissed.

4. Remaining Counterclaims

Bioheart asks for both prejudgment and postjudgment interest. In a diversity case, the awarding of prejudgment interest is controlled by state law. Hickson Corp. v. Norfolk S. Ry. Co., 124 Fed. App’x 336, 346 (6th Cir. 2005). Tennessee law allows the awarding of prejudgment interest “in accordance with the principles of equity” at a rate of not more than 10%

per annum. Tenn. Code Ann. § 47-14-123; see, e.g., Otis v. Cambridge Mut. Fire Ins. Co., 850 S.W.2d 439, 446 (Tenn. 1992). Exercising its equitable powers, the Court declines to award prejudgment interest since it has awarded Bioheart only declaratory relief and nominal damages. Postjudgment interest is mandatory under 28 U.S.C. §1961. Caffey v. Unum Life Ins. Co., 302 F.3d 576, 586 (6th Cir. 2002) (citations omitted). Accordingly, postjudgment interest shall be awarded and calculated at the rate set by 28 U.S.C. § 1961.

Bioheart also asserts claims which it states are only properly asserted against CTI, not Dr. Law or CTAL. Bioheart's post-trial filings request that the Court consider these claims if, and only if, it finds that CTI is properly before the Court and capable of asserting claims against Bioheart. Because CTI is in fact not properly before the Court, Bioheart's claims against CTI need not be considered, and those counterclaims are dismissed.

III. CONCLUSION

For the foregoing reasons, the Court finds that Plaintiffs have failed to establish the claims of their amended complaint, and all of Plaintiffs' claims are dismissed. Bioheart, however, has established its counterclaim seeking declaratory relief on the validity and enforceability of the Addendum. Bioheart has further established that Dr. Law has breached that part of the Addendum requiring him to provide "all pertinent and critical information" related to Bioheart's filing of an IND application with the FDA. Having proven entitlement to only nominal damages, the Court grants Bioheart a judgment against Dr. Law on these counterclaims in the amount of \$1.00 and awards postjudgment interest to be calculated according to 28 U.S.C. § 1961. All other counterclaims, including those made against CTI, are dismissed. Judgment shall be entered accordingly.

IT IS SO ORDERED this 13th day of March 2009.

s/Bernice Bouie Donald
BERNICE BOUIE DONALD
UNITED STATES DISTRICT JUDGE